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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,876	05/01/2001	Vahid Saadat	509192000100	5006

7590 07/27/2004  
JOHNEY U. HAN  
402 NOVATO AVENUE  
SUNNYVALE, CA 94086

EXAMINER
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IZAGUIRRE, ISMAEL

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/846,876	<b>Applicant(s)</b> SAADAT, VAHID	
	<b>Examiner</b> Ismael Izaguirre	<b>Art Unit</b> 3765	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 27 February 2004.

2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-57 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-22, 31-33, 35-49, 52-54, 56 and 57 is/are rejected.

7) ☒ Claim(s) 23-30, 34, 50, 51 and 55 is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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PTOL-326 (Rev. 1-04)

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Part of Paper No./Mail Date 20040723

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### **DETAILED ACTION**

The examiner is appreciative of the changes made to the language of the claims. These have been duly noted and considered.

### **CLAIMS**

#### **Summary**

Claims 1 and 38 are the independent claims under consideration in this Office action.

Claims 2-37 and 39-57 are the dependent claims under consideration in this Office action.

Concerning the patentability of the claims, the following is submitted for applicant's consideration:

#### **Claim Rejections - 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-22,31-33,35-49,52-54,56 and 57 are rejected under 35 U.S.C. § 102(e) as being anticipated by Greenhalgh (6,346,117).

Greenhalgh teaches an embolizing device for insertion into an aneurysm. Greenhalgh teaches a least one detachable self-expanding member 78 (see figure 11) configured to be sealed within a membrane 42. The member is defined as self-expanding (column 8, line 39) and includes a self-expanding wire structure in the form of a coil. The membrane is defined as an expandable bag having a volume including an opening (column 7, lines 46-47).

The self-expanding member 78 comprises a structure such that it includes a first configuration conforming to the internal shape of a positioning catheter 26 having a tubular cross-section. In the first configuration, the member including the membrane is fed to the site intended through the tubular internal cavity of the catheter (see figure 5, for example). In the second configuration the wire member 78 self-expands and fills the membrane at the aneurysm site.

Re claims 2, and 13-15, the coil 78 is taught as attached to a feeding wire and "snaked" up the catheter. When the self-expanding member is in place, the wire is released (column 9, line 34).

Re claim 4, Greenhalgh teaches that the expandable member 78 is formed of a great resiliency, high yield stress material and biocompatible.

Re claims 3,5,39,42 and 57, Greenhalgh teaches a stent or expanding member 78 and further teaches NiTi fibers or yarns enclosed or forming part of the bag 42. These NiTi elements are self-expanding for aiding the bag to expand. These constitute the second of the at least two members.

Re claims 6-8,33,40,43,53 and 54, the self-expanding member 78 is taught as being fed through a catheter in a first compressed configuration and then expanded in a second configuration. The physical structure of the member is taught as comprising a coil, a first diameter and then a second diameter (compressed and then expanded), which would touch the inner surface of the membrane. The cross-section of the member would include a circular shape. The final expanded shape would include a spherical shape.

Re claims 11-20,44,45 and 52, pushing the member through the catheter stimulates the member. The member 78 is taught as including a connection and is taught that it is released by mechanical or electrical current means (see column 2, lines 5-25). In the case of the electrical release, a current is passed through the catheter and erodes the connection point at the stent 78.

Re claims 21 and 22, the bag is taught as distensible and biocompatible (column 3, lines 31-38).

Re claims 31 and 32, the bag of Greenhalgh is taught as being formed of 5 to 100 denier and this anticipates these claims.

Re claims 35 and 36, the bag has an orifice of .005 inches, which would accommodate the wire to passing therethrough, which is taught as having a diameter of .005 inches (column 1, line 42).

Re claim 37, Greenhalgh teaches the bag including at least one main opening and being further porous for allowing blood to enter or aspirate into the bag and promote clotting. See column 6, line 65 and column 3, line 3.

Re claim 38, and 46-49, Greenhalgh teaches increasing a volume of a distensible member or bag 42 having at least one opening. Greenhalgh teaches the bag being porous (column 6, line 46) and allowing blood to aspirate (column 3, line 1) therethrough and aid in the clotting of the blood within the bag by electrothrombosis (column 9, lines 22-40). A self-expanding member is placed inside the bag and the bag itself is further provided with NiTi elements.

### **Comments**

Applicant notes that Greenhalgh teaches high porosity and as such does not aspirate fluid through the at least one orifice of the membrane, but instead allows fluid to pass in and out of the membrane unimpeded. Stating that the fluid flow is "unimpeded" simply means there is no impediment, obstruction or hindrance for preventing or stopping such flow into the membrane.

While it is true that fluid passes into the bag unimpeded (column 6, line 44), Greenhalgh, more importantly, teaches that the amount of porosity can be controlled by controlling the mesh density of the membrane and teaches an embodiment with a reduced porosity (column 6, lines 51-67). Aside from the porosity of the bag, it is clear

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that when the membrane is placed in the aneurysm initially, be there a small amount of fluid within the membrane or not, the membrane is caused to expand or self expands, and as the membrane expands, its braiding structure is such that the braid angles increase which increases the spaces between the braids. These spaces allow the "drawing" or "aspirating" of the fluids within the aneurysm into the membrane itself. The pressure difference noted by applicant exists within the membrane and this allows the fluids to enter the membrane, this is clear especially since Greenhalgh does not teach a positive pressure (be it gas or fluid) within the membrane which would push outwardly and not let fluid that is outside the membrane enter into the membrane. Accordingly, the claims are anticipated by Greenhalgh since the membrane of Greenhalgh "is adapted to reduce a pressure within the volume when reconfigured (expanding) such that fluid is aspirated through the at least one orifice into the volume".

#### **ALLOWABLE SUBJECT MATTER**

Claims 23-25,27-30,50,51 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **STATUS**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

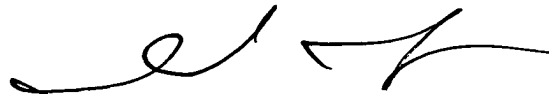
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **INQUIRIES**

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0861.

Any inquiry concerning this communication or earlier communications directed to the examiner should be directed to Mr. Ismael Izaguirre at (703) 308-0892 located in CP2-4B18, Monday through Friday 9:30am to 6:00pm.



**Ismael Izaguirre  
Primary Examiner  
Group Art Unit 3765**